

Appl. No. : 10/824,933
Filed : April 15, 2004

REMARKS

In response to the Office Action mailed March 21, 2007, Applicant respectfully requests that the Examiner reconsider the above-captioned patent application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 1-47 remain pending. Claims 1, 9, and 31 have been amended. New Claims 46-48 have been added.

The results of the Office Action mailed March 21, 2007 are summarized as follows:

CLAIM NOS. (Original Claims)	DISPOSITION/REJECTION		
	BASIS	PRIMARY REFERENCE	SECONDARY REFERENCE(S)
1-8, 41, 45	102(e)	Sterling (2003/0090649)	n/a
9-12, 31-37, 40 and 42-44	102(b)	Jina US 5,526,120	n/a
13, 38-39	103(a)	Jina US 5,526,120	Douglas US 5,962,215
14-18, 21	102(b)	Douglas US 5,962,215	n/a
19-20	103(a)	Douglas US 5,962,215	Sterling (6,312,888)

Claim 1 vs. Sterling (102(e))

Claim 1, as amended, clarifies that the identifying compound is not "blood components." In the cited reference, blood components are analyzed, but those blood components do not meet the limitations of the claims. Claims 41 and 45 are patentable for at least the same reasons given above for Claim 1.

Claim 9 vs. Jina (102(b)):

The rejection of Claim 9 over Jina is incorrect because Jina teaches a "detectable means" 58/62 for ascertaining proper orientation and/or insertion of a test strip in a meter, not a physical property of the test strip. Using the system taught in the Jina reference, a strip could be faulty or incorrect. As long as the strip was fully inserted into the device, a measurement could be taken, even though the strip itself (about which the detectable means 58/62 conveys nothing) was faulty or incorrect. The strip could thus have improper physical characteristics (e.g., incorrect absorption

properties of the window, incorrect path length, incorrect sample chamber thickness, etc.) which could lead to inaccurate measurements, and the system would allow the user to proceed as if all was normal. For example, under the teachings of Jina, a counterfeit test strip that had been cut to the same shape and dimensions as a proper test strip would not be identified as counterfeit. Thus, Jina does not teach the limitations of the claims.

Claim 10 is patentable for at least the reasons given above with respect to Claim 9. Furthermore, Figures 1 and 5-12 of Jina do not anticipate the additional limitation of Claim 10 because those figures merely show windows in an optical path. This does not disclose or suggest the limitations of the claims.

Claims 11 and 12 are patentable for at least the reasons given above with respect to Claim 9. Furthermore, Figures 7-12 of Jina do not anticipate the additional limitations of Claims 11 and 12; those figures merely show windows in an optical path.

Claims 13 and 38-39 vs. Jina in view of Douglas (103(a)):

Dependent Claim 13 is patentable for at least the reasons given above with respect to Claim 9. The Douglas reference merely discloses calibration, not the limitations of the claims.

Claims 38-39 depend from amended Claim 31. Neither the Jina reference nor the Douglas reference discloses or suggests “qualifying [a] sample element” by “determining a characteristic of the portion of the sample element in the optical path” where the optical path is “for determining analyte concentration.” Moreover, neither reference teaches the other limitations of the claims. For at least these reasons, claims 38 and 39 are patentable over Jina in view of Douglas.

Claim 14 vs. Douglas (102(b)):

In contrast to the limitations of Claim 14, Douglas teaches including a “barcode on strip” or a “magnetic strip” to provide “calibration information” or “start of test signals.” Douglas, Col. 24, lines 43-48. Thus, Douglas does not teach an “identification key.” Moreover, Douglas teaches away from the limitation that the identification key is “located...in an optical path for analyte measurement” because if placed in an optical path for analyte measurement, both the barcode and magnetic strip of Douglas would interfere with and vitiate any optical measurements. For this same reason, the calibration data of Douglas does not indicate a “qualification state” of the sample element. Moreover, Douglas does not teach the other limitations of Claim 14. Dependent Claims

Appl. No. : **10/824,933**
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15-18 and 21 are patentable for at least the reasons provided here with respect to Independent Claim 14.

Claims 19-20 vs. Douglas and Sterling (103(a)):

Claims 19 and 20 depend from Claim 14. Thus, Claims 19 and 20 are patentable over the Douglas reference for the same reasons given above with respect to Claim 14. Moreover, consistent with the discussion of Claim 1 above, the “blood components” described in the Sterling reference are potential analytes, not an “identification key” as claimed. Moreover, the other limitations of Claims 19 and 20 are not taught or suggested by these references. Thus, Claims 19 and 20 are patentable over the combination of the Douglas and Sterling references.

Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is requested.

Applicant respectfully traverses each of the Examiner’s rejections and each of the Examiner’s assertions regarding what the prior art shows or teaches. Although amendments, deletions and cancellations have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments, deletions and cancellations are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant’s attorney, William B. Bunker, at (949) 721-2839 to resolve such issue(s) promptly.

Appl. No. : 10/824,933
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: _____

9/21/07

By: _____



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